

## **2 IN 1 DANDRUFF- pyrithione zinc shampoo**

**Vi-Jon**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Dandruff Shampoo Clean Apple Scent**

#### **Active ingredient**

Pyrithione zinc 1%

#### **Purpose**

Anti-dandruff

#### **Use**

helps prevent recurrence of flaking and itching associated with dandruff

#### **Warnings**

**For external use only**

#### **When using this product**

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

#### **Stop use and ask a doctor if**

- condition worsens or does not improve after regular use as directed

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- shake well
- for maximum dandruff control, use every time you shampoo
- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor

#### **Inactive ingredients**

water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, sodium chloride, zinc carbonate, sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, citric acid, methylchloroisothiazolinone, methylisothiazolinone, blue 1, yellow 5

#### **adverse reaction**

Multiple benefit formula to help:

- Fight dry scalp
- Calm itch
- Relieve irritation
- Soothe and reduce redness
- Reduce oiliness
- Prevent flakes
- Leave hair healthy looking

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Head and Shoulders Green Apple 2 in 1 Pyrithione Zinc Dandruff Shampoo and Conditioner.

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

Made in the USA with US and foreign parts.

612.001/612AC

### **principal display panel**

mountain

falls

Compare to Head & shoulders

helps prevent flakes

+ conditioner

paraben free

pH balanced formula

2 in 1

dandruff shampoo

with pyrithione zinc

clean apple

23.7 FL OZ (700 mL)



## 2 IN 1 DANDRUFF

pyrithione zinc shampoo

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-612
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-612-21	89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2016	
2	NDC:11344-612-92	399 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2016	
3	NDC:11344-612-35	700 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2016	
4	NDC:11344-612-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2016	
5	NDC:11344-612-39	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/06/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/06/2016	

**Labeler** - Vi-Jon (150931459)

**Registrant** - Vi-Jon (088520668)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(11344-612)

